

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

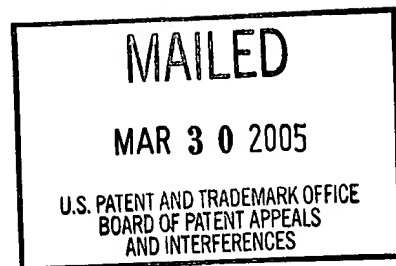
**UNITED STATES PATENT AND TRADEMARK OFFICE**

**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Ex parte CARL JOHAN FRIDDLE,  
ERIN HILBUN,  
BRENDA GERHARDT and  
C. ALEXANDER TURNER JR.

Appeal No. 2005-0731  
Application No. 09/974,712

ORDER UNDER 37 CFR § 41.50(d)



Before WILLIAM F. SMITH, ADAMS and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

ORDER UNDER 37 CFR § 41.50(d)

Under the provisions of 37 CFR § 41.50(d),<sup>1</sup> we require Appellants to address the following matters:

We invite attention to commonly assigned Application No. 09/714,882.<sup>2</sup> That application was the subject of an appeal to this board (Appeal No. 2004-1732), which was decided on September 24, 2004.

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<sup>1</sup> "The Board may order appellant to additionally brief any matter that the Board considers to be of assistance in reaching a reasoned decision on the pending appeal. Appellant will be given a non-extendable time period within which to respond to such an order." 37 CFR § 41.50(d).

The issues and arguments in Appeal No. 2004-1732 bear close resemblance to those in this appeal. In Appeal No. 2004-1732, the broadest independent claim (claim 2) was directed to “[a]n isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence shown in SEQ ID NO:2.” The polypeptide of SEQ ID NO:2 was disclosed to have sequence similarity to Notch receptor ligands, but the specification did not disclose the biological function of the putative ligand. The only issue in Appeal No. 2004-1732 was whether the specification disclosed a patentable utility for the claimed invention.

In Appeal No. 2004-1732, the appellants argued, among other things, that the claimed nucleic acids had utility because they could be used in methods that do not depend on the biological activity of the encoded protein. The appellants argued that the claimed nucleic acids were useful “in determining the genomic structure of the corresponding human chromosome . . . , for example mapping the protein encoding regions” and that they “are useful for functionally defining exon splice-junctions.” Application No. 09/714,882, Board decision mailed 9/24/04, page 18.

The appellants in Appeal No. 2004-1732 also argued that the claimed nucleic acids could be used in “gene chips” or “DNA chips” to monitor gene expression. The appellants argued that “[s]uch “DNA chips” clearly have utility, as evidenced by hundreds of issued U.S. Patents. . . . Clearly, compositions that enhance the utility of

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<sup>2</sup> The named inventors in the instant application are Carl Johan Friddle, Erin Hilbun, Brenda Gerhardt, and C. Alexander Turner, Jr. In Application No. 09/714,882, the inventors are C. Alexander Turner Jr., Michael C. Nehls, Glenn Friedrich, Brian Zambrowicz, and Arthur T. Sands.

such DNA gene chips, such as the presently claimed sequences encoding a testis specific Notch ligand, must in themselves be useful." Id.

Finally, the appellants argued that Appellants the claimed polynucleotides were useful because of a disclosed polymorphic position in SEQ ID NO:1: "the skilled artisan would readily recognize and easily believe that the presently described polymorphic markers [sic] could be useful in forensic analysis. The fact that forensic biologists use polymorphic markers such as those described by Appellants every day provides more tha[n] ample support for the assertion that forensic biologists would also be able to use the specific polymorphic markers [sic] described by Appellants in the same fashion." Id., page 16.

The panel that decided Appeal No. 2004-1732 reviewed governing principles of law; addressed and rejected the appellants' arguments premised on DNA chips, gene mapping, and exon splice junctions; and concluded that "Appellants' disclosure in th[at] case does not provide a specific benefit in currently available form, and therefore lacks the substantial utility required by 35 U.S.C. § 101." Id., page 27. Accordingly, the examiner's decision, rejecting all of the pending claims in Application No. 09/714,882, was affirmed.

Like the claims in Application No. 09/714,882, in this appeal the broadest independent claim (claim 3) is directed to a nucleic acid comprising a nucleotide sequence that encodes the amino acid sequence of SEQ ID NO:2. The specification discloses that SEQ ID NO:2 "shares structural similarity with mammalian ion channel proteins . . . and more particularly voltage-gated potassium channel proteins." See page

2. All of the claims on appeal stand rejected on the basis that the specification does not disclose a patentable utility for the claimed invention. Examiner's Answer, page 3.

The Appeal Brief in this appeal includes essentially the same arguments that were made and rejected by the previous merits panel in Appeal No. 2004-1732.<sup>3</sup> For example, Appellants argue that:

- "Clearly, the present polynucleotide provides exquisite specificity in localizing the specific region of the human chromosome containing the gene encoding the given polynucleotide. . . . The presently claimed polynucleotide sequence defines a biologically validated sequence that provides a unique and specific resource for mapping the genome." (Appeal Brief, pages 21-22);
- "[T]he described sequences are useful for functionally defining exon splice-junctions." (id., page 22);
- "[T]he present nucleotide sequence would be an ideal, novel candidate for assessing gene expression using, for example, DNA chips. . . . Such 'DNA chips' clearly have utility, as evidenced by hundreds of issued U.S. Patents. . . . Clearly, compositions that enhance the utility of such DNA chips, such as the presently claimed sequences encoding a voltage gated ion channel (KCNA7) associated with human heart disease, must in themselves be useful." (id., pages 19-20);
- "[T]hose of skill in the art would readily recognize that the presently described polymorphisms, exactly as they were described in the specification as originally filed, are useful in forensic analysis, population biology and paternity analysis to specifically identify individual members of the human population based on the presence or absence of the described polymorphism." (id., page 16).

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<sup>3</sup> In addition to the arguments summarized above, Appellants argue that the claimed polynucleotides have utility because the encoded protein is a variant of the potassium channel protein KCNA7, which has been associated with a certain heart disorder. See the Appeal Brief, pages 7-8. Appellants cite a GenBank entry and a scientific paper as support for this position but neither provides the required evidentiary support. The GenBank entry bears a submission date of October 23, 2000, which is later than the effective filing date of the instant application (which claimed priority to a provisional application filed October 10, 2000). Likewise, the scientific paper was published in January 2002, well after the effective filing date. "Enablement, or utility, is determined as of the application filing date." *In re Brana*, 51 F.3d 1560, 1567 n.19, 34 USPQ2d 1436, 1441 n.19 (Fed. Cir. 1995). Since neither the GenBank entry nor the scientific paper were known to those skilled in the art as of the effective filing date, they cannot be relied on to support utility. In addition, we note that the paper cited by Appellants as showing an association between KCNA7 and a heart disorder (progressive familial heart block I, or PFHBI) in fact states that the disclosed results "provide evidence for the exclusion of this candidate [KCNA7] as the PFHB1-causative gene" (emphasis added).

On these facts, we require Appellants to explain why we should again address the same line of argument in this case: since the same arguments were considered and thoroughly addressed in Appeal No. 2004-1732, why would the previous panel's treatment of those arguments not be dispositive here? In particular, why should the facts and arguments set forth in the briefing of this appeal lead to a different conclusion than that reached by the panel in Appeal No. 2004-1732, which rejected the same arguments? We note that, according to PTO records, the appellants in Appeal No. 2004-1732 (Application No. 09/714,882) did not request rehearing under 37 CFR § 41.52, nor did they appeal the Board's decision, within two months from the date of the Board decision.

#### Conclusion

In conclusion, we require Appellants to address the foregoing matters "consider[ed] to be of assistance in reaching a reasoned decision on the pending appeal." 37 CFR § 41.50(d). We caution, however, that this is not an invitation to expand on points raised in the Appellants' brief or to rehash arguments already set forth in the brief. This is not an invitation to raise arguments or issues on appeal, or to collaterally attack the decision in Appeal No. 2004-1732. See 37 CFR § 41.37(c)(1)(vii) ("Any arguments or authorities not included in the brief or a reply brief filed pursuant to § 41.41 will be refused consideration by the Board, unless good cause is shown"). Appellants' response should be confined to the matters outlined above.



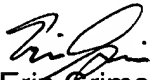
Time Period For Response

A period of one month from the date of this order is set for Appellants' response.

This time is non-extendable.

Failure to respond in a timely manner will result in dismissal of the appeal.

37 CFR § 41.50(d)

	)	
William F. Smith	)	
Administrative Patent Judge	)	
	)	
Donald E. Adams	)	BOARD OF PATENT
Administrative Patent Judge	)	APPEALS AND
	)	INTERFERENCES
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EG/jlb

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